Medicare+Choice Organizations and Medicare coverage of routine costs of clinical trials
Questions and Answers.

Q1. Do Medicare+Choice organizations need to cover the routine costs of clinical trials described in the National Coverage Determination (NCD)?

A1. Medicare rules provide that if an NCD meets a threshold for significant cost, Medicare will pay for these services outside of the capitated payments until the first opportunity when the costs for these services can be figured into the capitated payments. The coverage included in the clinical trials NCD met the significant cost threshold, and Medicare will be paying providers directly for these services.

Q2. May an M+C enrollee participate in clinical trials even when the providers in the trial are not in the M+C organization's network?

A2. Yes. Medicare regulations require that NCD services be furnished to M+C enrollees even when these services cannot be furnished though an M+C organization network. The nature of clinical trials is such that many of these services only will be available and accessible to M+C enrollees when furnished by out-of-network providers. For this reason, coverage cannot be limited to trials in which the M+C organization itself may participate or to trials in which M+C organization network providers may participate.

Q3. Does the fact that Medicare will be paying for the routine costs of clinical trials on a fee-for-service basis mean that all services for M+C enrollees in clinical trials may be billed in this way?

A3. No. There is no change in M+C organizations' obligation to provide all other benefits that are covered under the contract to beneficiaries who participate in these clinical trials.

Q4. Medicare+Choice organizations are concerned about losing track of the services and care being provided to members who participate in clinical trials when the organizations do not pay for the services. What can Medicare+Choice organizations do to follow these M+C members?

A4. HCFA's payments for clinical trial services directly to providers in the short term may make it hard for M+C organizations to track and coordinate the care for these beneficiaries. M+C organizations may set up a notification process to collect information about which members are in a clinical trial, and which clinical trial they are in. This notification process may not be used in any way as a pre-authorization mechanism, however.

In addition, the Agency for Health Research and Quality will be developing a registry of approved clinical trials. Once this is developed, M+C organizations and others will be able to use this registry to contact the trial sponsors in the clinical trial to learn more about the nature of the trial, the services that will be furnished, and the providers who are participating.

Q5. M+C organizations are very concerned about how they are going to cover these services once they are included in capitation payments. How are M+C organizations' questions going to be resolved?

A5. M+C organizations and their representatives have raised many important questions about how this will work, and HCFA will continue ongoing discussions with industry representatives to resolve operational issues. HCFA will be developing answers to questions of this nature that were submitted as a part of the comment process for the NCD and publishing them on an ongoing basis on the hcfa.gov web site.

Q6. How will payments to providers be calculated?

A6. Payment for clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans is determined according to the applicable fee-for-service rules, except that M+C enrollees are not responsible for meeting either the Part A or Part B deductible (i.e., the deductible is waived). M+C enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.

Q7. How will intermediaries and carriers recognize bills for the routine costs of clinical trials?

A7. Please refer to the procedures described in the program memorandum describing implementation of clinical trials coverage. This is available at http://www.hcfa.gov/quality/8d3.htm.

Q8. What happens if providers forget to put these codes on their bills?

A8. Bills/services that are not coded accordingly will not be paid; however providers may resubmit the claims with the clinical trials codes if they were inadvertently omitted.

Q9. What should M+C organizations do if clinical trial providers send them bills?

A9. If a provider sends a bill with the clinical trial codes on it to an M+C organization, the M+C organization should not pay it. Instead, the organization should inform the provider that the bill should be submitted to the appropriate intermediary or carrier. Of course, M+C organizations continue to be responsible for all other

benefits that are covered under the contract to beneficiaries who participate in the clinical trials.

Q10. Some of the providers in an M+C organization network are involved in clinical trials but are not enrolled as Medicare providers. What do they need to do to enroll?

A10. Providers serving managed care enrollees receiving clinical trial services must be enrolled with Medicare in order to bill on a fee-for-service basis for those services. Providers that wish to bill but that have not yet enrolled with Medicare should contact their local carrier, intermediary, or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Q11. What should M+C organizations tell beneficiaries about this new coverage?

A11. In their next regularly scheduled communication with members, M+C organizations must inform that Medicare is now covering certain services related to clinical trials. M+C organizations should also inform their Medicare members that beneficiaries are responsible for paying the coinsurance that applies for fee-for-service benefits when those benefits are provided as part of a clinical trial. In other words, any plan-defined cost sharing would not apply.

M+C organizations are not responsible for making up the difference between the Medicare fee-for-service cost sharing and any plan cost sharing that would apply to that type of service. HCFA will be collaborating with M+C organizations, clinical trial sponsors, and groups that work with beneficiaries to educate beneficiaries about their financial liabilities when they enter a clinical trial.

If M+C members ask their organizations for information on Medicare coverage of these clinical trials services, the organizations may wish to direct them to 1-800-MEDICARE for more information.

Q12. Do M+C organizations need to furnish non-Medicare benefits as part of the routine costs of clinical trials?

A12. No. Until the costs of clinical trials' services are factored into M+C capitated payment rates, M+C organizations are not obligated to furnish any additional or supplemental benefits as routine costs of clinical trials.

Q13. Are M+C organizations responsible for submitting encounter data for these services?

A13. No. M+C organizations are not responsible for submitting encounter data from clinical trial providers. Because HCFA will be making fee-for-service payments directly to providers for clinical trials services, the information needed for risk adjustment (diagnoses and other data elements) will already be present in HCFA's systems.

Q14. Where can M+C organizations go to get more information on clinical trials?

A14. If M+C organizations or other entities have further questions regarding the coverage of clinical trials and their responsibilities regarding this coverage they may send an e-mail to clinicaltrials@hcfa.gov or contact their plan manager.